K011238

JAN 0 8 2002

Attachment 1: 510(k) Summary

510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Submitter:

Metracor Technologies, Inc.
11425 Sorrento Valley Road
San Diego, CA 921221
Tel: (619) 793-3300
Fax: (619) 793-3315
Contact Person: George McHugh, Vice President, Operations

Date Prepared:

January 3, 2002

Name of Device and Name/Address of Sponsor

Device Name:

RODA® Monitoring System

Sponsor:

Metracor Technologies, Inc.
11425 Sorrento Valley Road
San Diego, CA 921221

Common or Usual Name

RODA®

Classification Name

INFUSION PUMP, ANALYTICAL SAMPLING--21 C.F.R. § 880.5725

PREPROGRAMMED DIAGNOSTIC COMPUTER-- 21 C.F.R. § 870.1435

INDWELLING BLOOD CARBON DIOXIDE ANALYZER--21 C.F.R. § 868.1150

INDWELLING BLOOD OXYGEN PARTIAL PRESSURE ANALYZER--21 C.F.R. § 868.1200

Predicate Devices

1. Metracor Technologies, Inc. VIA 1-01 Infusion Pump/Blood Chemistry System (K935778)
2. Baxter Healthcare Corporation Model COM-3 (K896930)
3. Cardiodynamics International Corporation BioZ System (K963183)
4. Pulsion Continuous Pulse Contour Cardiac Output Monitor (K001762)
5. Lidco, Ltd. PulseCO Hemodynamic Monitor CM71 (K010049)
6. Sorba Medical Systems, Inc. Model CIC-1000 (K895017)
7. Renaissance Technology, Inc. IQ System (K981720)
8. Pulse Metric Dyna Pulse Pathway (no 510(k))

Intended Use

The *RODA®* Monitoring System *(RODA®)* is an integrated medical device intended for the real-time, on-line monitoring and trending of hemodynamic parameters (including cardiac output), arterial blood gases, hemoglobin and blood chemistry, when used in conjunction with a preexisting radial arterial line.

Technological Characteristics

RODA® operates by utilizing a peristaltic pump connected to an arterial catheter to withdraw a small amount of blood, which then comes in contact with an in-line electrochemical sensor set. An array of sensors analyzes the sample for arterial blood gases, electrolytes, glucose, and hematocrit, and the measured and/or derived values are displayed on a monitor after approximately 1 minute. The pump and sensors operate in a closed system; thus, when analysis is completed, the blood is returned to the patient. The values produced by analysis of the arterial blood are applied to standard equations to display oxyhemoglobin saturation and oxygen content.

Automated sampling can be performed at preset intervals or manually (with a minimum interval of 10 minutes). *RODA®* can also be connected to a temperature probe (not supplied with *RODA®)* to provide a body temperature measurement to increase the accuracy of calculated oxyhemoglobin saturation.

When used for hemodynamic monitoring, the amplified signal from a pressure transducer (not supplied with *RODA®*) connected to the radial artery catheter provides the source for measured systolic, diastolic, and mean blood pressures, and heart rate. The pressure signal is also used by the system to monitor and trend cardiac output, which is determined by an algorithm that converts arterial pressure into aortic flow. *RODA®* displays measured and derived hemodynamic parameters on a beat-to-beat basis and automatically displays and trends oxygen delivery, the product of the cardiac output and arterial oxygen content, calculated from parameters determined from the most recent blood withdrawal.

Summary Basis for the Finding of Substantial Equivalence

RODA® has the same intended use and indications for use as the predicate devices. All of the predicates, like *RODA®*, are indicated for use in monitoring hemodynamic and/or blood chemistry parameters. In addition, the parameters measured by *RODA®* are identical to the parameters measured by the predicates. Most of the technological features of *RODA®* are substantially equivalent to the predicate VIA LVM System. The *RODA®* System also has the ability to monitor cardiac output. Predicate devices such as the Baxter COM-3 and the Pulsion and PulseCO Monitors also perform this function. Like predicate devices, the *RODA®* System derives cardiac output by mathematical analysis of an arterial blood pressure signal. In clinical testing, the algorithm used in *RODA®* has been validated for use to monitor stroke volume (SV), and therefore cardiac output, without calibration to thermodilution in patients aged 20-78 with stroke volumes ranging from 29.9-141.2 ml with acceptable accuracy and reproducibility. The range of cardiac output values as determined by thermodilution observed in the clinical testing was 2.0-9.3 L/min.1/

Thus, *RODA®* is substantially equivalent to a combination of the predicate devices cited.

1/ Jansen JRC *et al.* A comparison of cardiac output derived from the arterial pressure wave against thermodilution in cardiac surgery patients. Br. J. Anaesthesia. 87(2): 212-22 (2001).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2002

Mr. George McHugh
Vice President
Metracor Technologies
11425 Sorrento Valley Road
San Diego, CA 92121

Re: K011238
Trade Name: RODA® (Real Time Oxygen Dynamics Analysis) Monitoring System
Regulation Number: 21 CFR 870.1435 and 868.1200
Regulation Name: Single-Function Preprogrammed Diagnostic Computer and Indwelling Blood Oxygen Partial Pressure Analyzer
Regulatory Class: Class II (two)
Product Code: 74 DXG and 73 CCE
Dated: October 10, 2001
Received: October 10, 2001

Dear Mr. McHugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

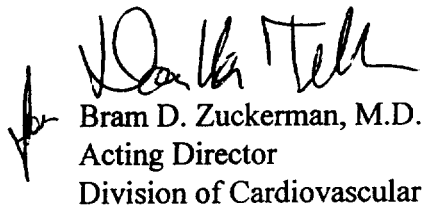
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011238

Device Name: RODA® (Real Time Oxygen Dynamics Analysis) Monitoring System

Indications For Use:

The RODA® Monitoring System is indicated for the real-time, on-line monitoring and trending of hemodynamic parameters, arterial blood gases, hemoglobin and blood chemistry when used in conjunction with a preexisting radial artery line. The device is specifically indicated for use to monitor cardiac output and trends in cardiac output.

The parameters measured by the system are listed below

- Arterial blood gases
  - Oxygen partial pressure (PaO2)
  - Carbon dioxide partial pressure (PaCO2)
  - pH
- Electrolytes
  - Na+, K+, Ca++
- Hematocrit (Hct)
- Glucose
- Arterial blood pressure
  - Systolic
  - Diastolic
  - Mean
- Heart rate (HR)
- Body temperature (T)

Parameters calculated or derived by the system

Stroke volume (SV)
Stroke volume index (SVI)
Cardiac output (CO)
Cardiac index (CI)
Systemic vascular resistance (SVR)
Systemic vascular resistance index (SVRI)
Hemoglobin concentration [Hb]
Arterial oxyhemoglobin saturation (SaO_2)
Arterial oxygen content (CaO_2)
Alveolar-arterial oxygen partial pressure gradient (A-a gradient)
Oxygen delivery (DO_2)
Total carbon dioxide (TCO_2)
Bicarbonate concentration [HCO_3^-]
Base deficit (BD)
Partial pressure of alveolar oxygen (PAO_2)
PaO_2/FiO_2 ratio (P/F)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011238

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)